



Standards Coordination Office



Basics of Conformity Assessment

June 23, 2016

Objectives

You will be able to:

- identify a variety of types of conformity assessment
- list international standards for conformity assessment
- describe the relationship among parties involved in a conformity assessment system

Today's Discussion

- Terminology
- Types of Conformity Assessment
- How it Works
- Examples

Conformity Assessment

“demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled”

- *ISO/IEC 17000*

1st Party

2nd Party

3rd Party

The Parties – who done it?

First Party

A seller or manufacturer

Second Party

A purchaser or user

Third Party

An independent entity that has no interest in transactions between the first and second parties

Government

Has a unique role in regulation, but is the second party in procurement application of standards

1st Party

2nd Party

3rd Party

Types of Conformity Assessment

- Supplier's Declaration of Conformity (SDoC)
- Inspection
- Testing
- Certification
- Registration
- Accreditation
- ISO/IEC 17050 parts 1 and 2
- ISO/IEC 17020
- ISO/IEC 17025
- ISO/IEC 17065
- ISO/IEC 17021
- ISO/IEC 17011

Supplier's Declaration of Conformity (SDoC)

1st Party

2nd Party

3rd Party

Characteristics

- Used when low product risk
- Penalties for noncompliant products
- Effective recall system

Examples



- ISO/IEC 17050

Inspection

1st Party

2nd Party

3rd Party

Characteristics

Examples

- Simple test measurement or examination
- Code compliance

- *ISO/IEC 17020*



Testing

1st Party

2nd Party

3rd Party

Characteristics

Examples

- Characteristics are measured
- Representative samples are often used
- May be used in a SDoC or certification system

- *ISO/IEC 17025*



Certification

1st Party

2nd Party

3rd Party

Characteristics

- moderate – high product risk
- Generally, more expensive
- Surveillance

- ISO/IEC 17065

Examples



Management System Registration

Characteristics

- Requirements are Process requirements
- Scopes can be general or specific

- *ISO/IEC 17021*

Examples



Accreditation

1st Party

2nd Party

3rd Party

Characteristics

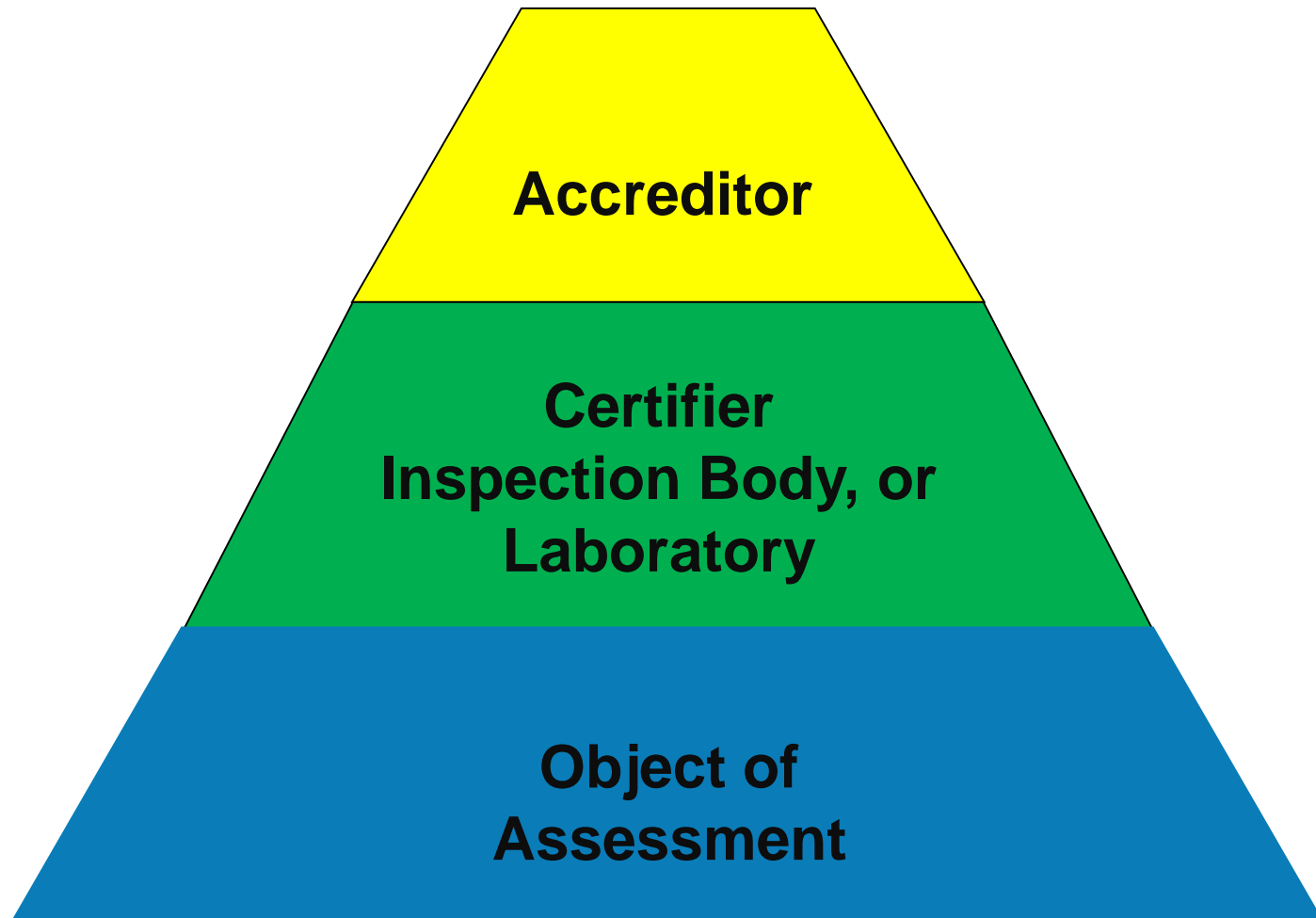
- Formal demonstration of competence
- Confidence for purchasers, regulators and consumers

- *ISO/IEC 17011*

Examples



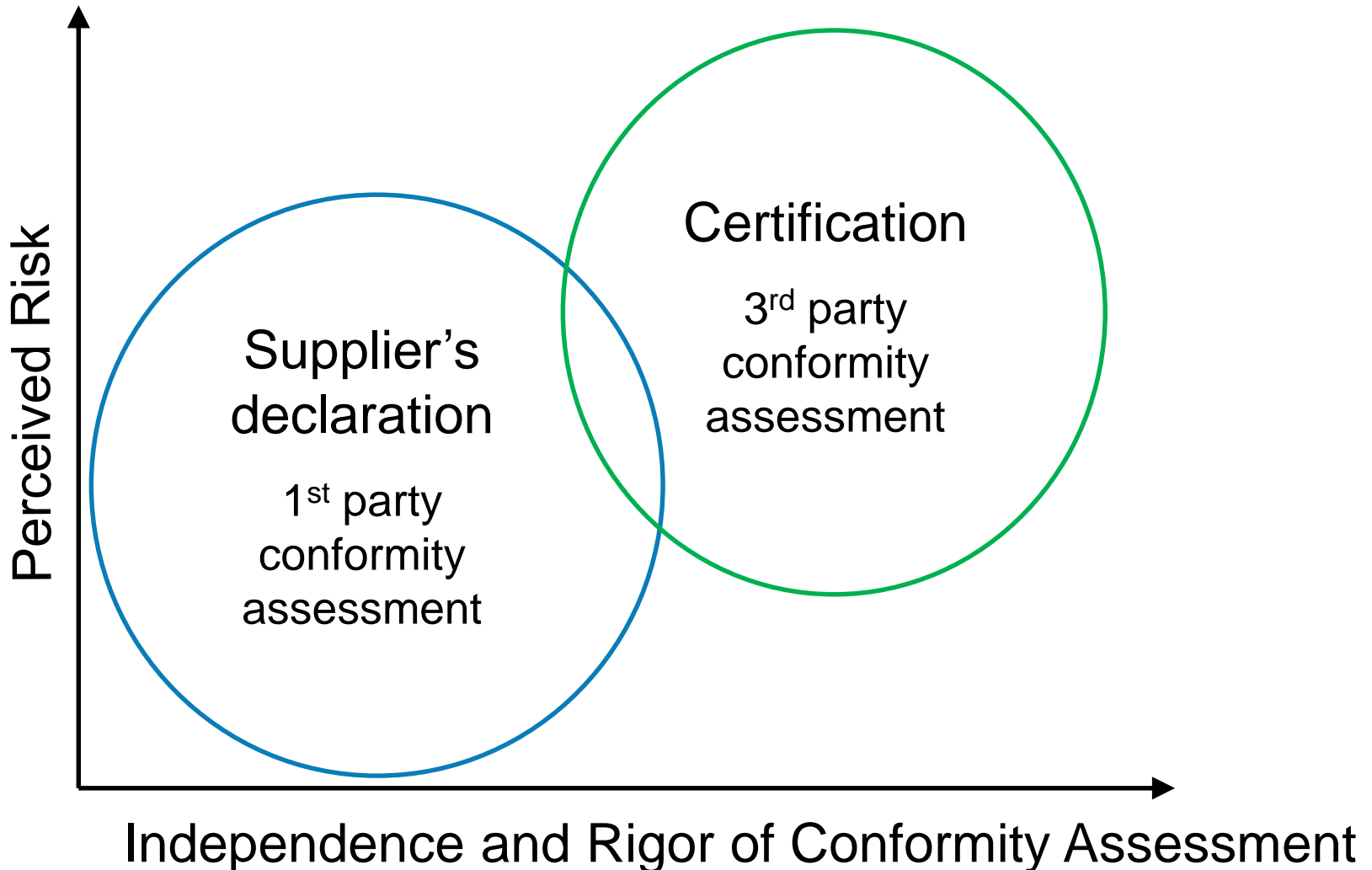
Who watches the watchers?

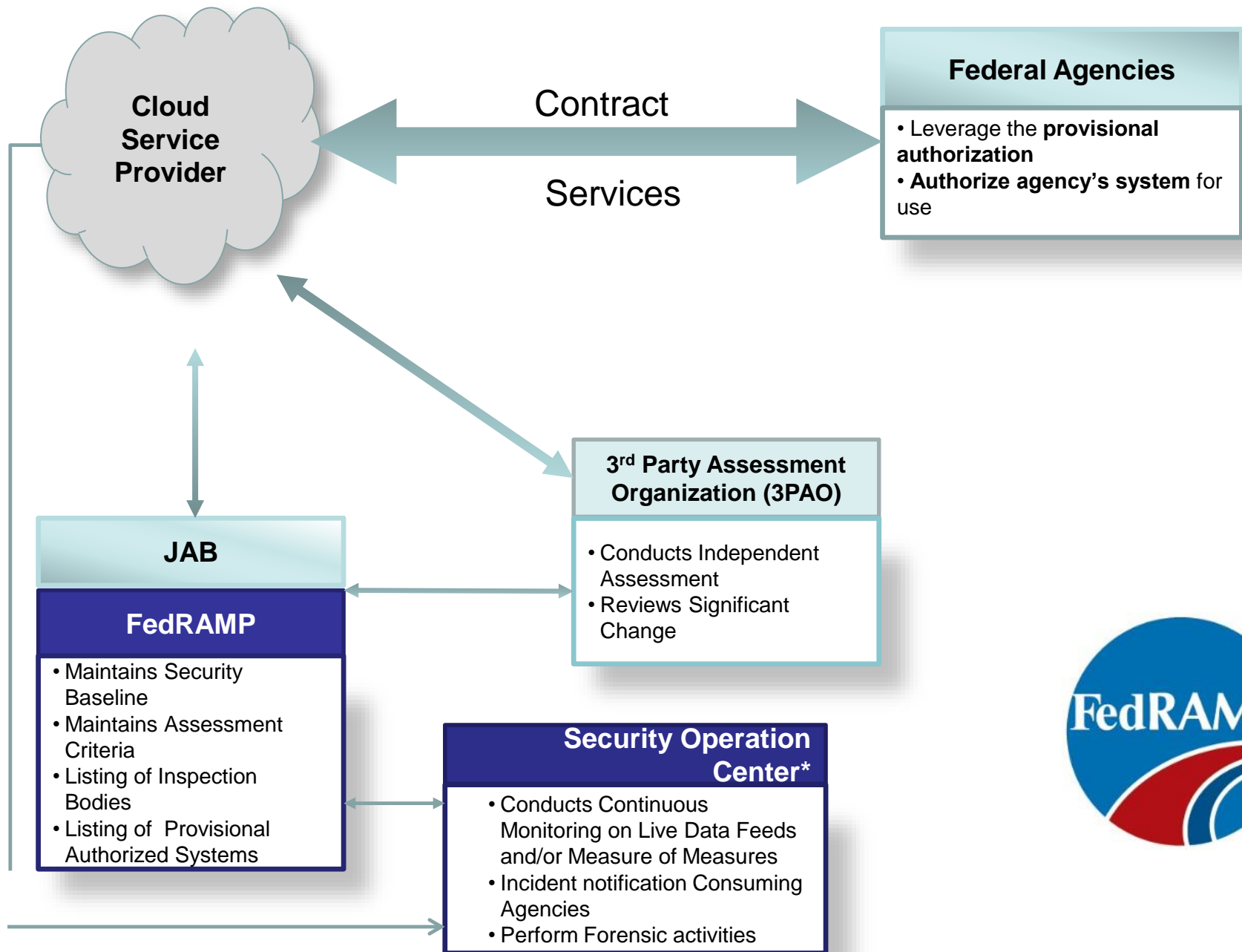


Factors in Conformity Assessment Systems

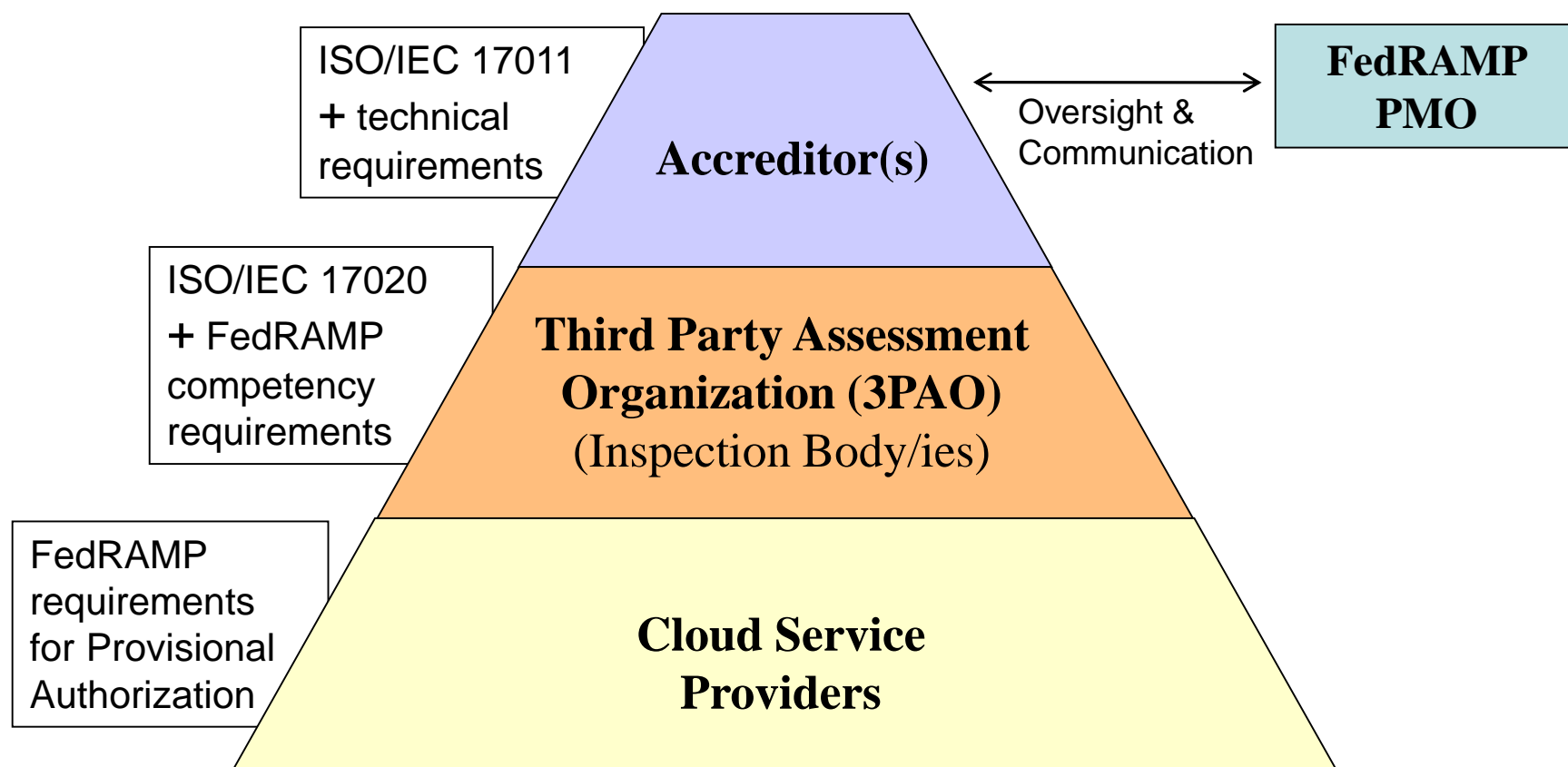
- Risks associated with non-compliance should be proportional to the rigor of the system design
 - ▶ Over-design costs too much
 - ▶ Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor

How much confidence is needed?





FedRAMP 3PAO Hierarchy



ISO/IEC 17011; Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020; General criteria for the operation of various types of bodies performing inspection

Review

- Terminology
- Types of conformity assessment
- How it works
- Examples

Thank You

Basics of Conformity Assessment

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